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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,481	06/23/2003	Andrew Fensome	AHPWA25AUSA	8944
38199	7590	09/08/2004	EXAMINER	
HOWSON AND HOWSON			HENLEY III, RAYMOND J	
CATHY A. KODROFF				
ONE SPRING HOUSE CORPORATE CENTER				
BOX 457				
SPRING HOUSE, PA 19477			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 09/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/601,481	FENSOME ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 August 2004.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16 and 25-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/10/2004.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**CLAIMS 1-16 AND 25-28 ARE PRESENTED FOR EXAMINATION**

Applicants' Amendment filed August 4, 2004 and Information Disclosure Statement filed August 10, 2004 have been received and entered into the application. Accordingly, claims 1 and 28 have been amended. Also, as reflected by the attached, completed copy of form PTO-1449 (or equivalent thereof), the cited references have been considered.

In light of Applicants' Amendments, the claim rejection under 35 U.S.C. 112, second paragraph, as set forth in the previous Office action, is withdrawn.

***Claim Rejection - 35 USC § 103***

Claims 1-16 and 25-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/66570 and applicants' acknowledgment at page 4, lines 3-5 of the present specification in view of Gast et al. (U.S. Patent Application Publication No. 2002/0061875), each of record, for the reasons of record as set forth in the previous Office action.

Applicants' arguments at pages 18-19 of the amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicants have argued that neither the '570 reference nor Gast teach or suggest any specific progestins that can be utilized for contraception when combined with a selective estrogen receptor modulator. It has also been argued that in the present rejection, the Examiner is required to consider the size of the genus of progestins and that there must be motivation to select the claimed species of subgenus in the prior art.

In response thereto, the Examiner's position is that because the '570 reference teaches the presently claimed compounds as progestin agonists ('570 at the abstract, for example) and that

progestin agonists may be used in methods of contraception when combined with an estrogen agonist (page 1 of the '570 reference, lines 29-30), the propriety of instant conclusion of obviousness remains. That applicants may wish to characterize the teachings of the reference as being insufficient to support a conclusion of obviousness is not persuasive. Further, the genus of the progestin agonists taught by the '570 reference has again been considered by the Examiner, but is not seen to be so large that it would not have taught that applicants' claimed compounds are progestin agonists. Especially when applicants themselves have admitted at page 4, lines 3-5 of the present specification that the '570 reference teaches the presently claimed compounds.

Accordingly, for the above reasons, the claims are deemed properly rejected.

***Double Patenting***

Claims 1-16 and 25-27 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91 and 92 and each of the claims directly and indirectly upon which they depend of U.S. Patent No. 6,436,929 (cited by applicants) in view of WO'570 and Gast et al. (U.S. Patent Application Publication No. 2002/0061875, cited by the Examiner).

In light of the fact, as pointed out by applicants, that U.S. Patent No. 6,509,334 requires the equivalent to applicants' Q<sup>1</sup> to be oxygen and applicants' claim do not permit Q<sup>1</sup> to be oxygen, the Examiner no longer relies upon the '334 patent.

Applicants' arguments concerning the remaining references have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, applicants have initially argued that the Examiner has not provided an explanation of how the presently claimed subject matter would have been obvious over the references cited. At pages 5 and 6 of the previous Office action, the differences between the presently claimed subject matter and that of the prior art has been specified and an explanation of why such claimed matter would have been obvious has also been supplied. Thus, applicants' position is not well taken.

Applicant has also argued that since the '929 and '570 references have identical specifications, the compounds claimed in the '929 reference are identical to the '570 compounds and that neither the '929 and '570 reference teach or suggest the present invention. Applicants have not, however, explained how the claimed subject matter is not rendered obvious not only by the '929 or '570 reference but the combination of references relied upon by the Examiner. Accordingly, the Examiner maintains that the rejection is proper.

Also, applicant has argued that given the genus of progestins known in the art, the claimed subject matter would not have been obvious. However, given the reasonable size of the genus of progestins taught in the references relied upon, the rejection is deemed to remain proper.

Finally, applicants have argued that it would not have been obvious to substitute progestins with anti-progestins. The Examiner, however, has not proposed that it would have been obvious to do this. Accordingly, Applicants' positions is not well taken.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

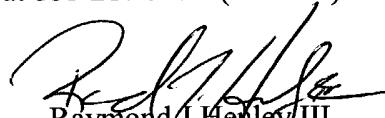
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III  
Primary Examiner  
Art Unit 1614

August 30, 2004